AF

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,180	10/18/2001	Lydie Bougueleret	GEN-100D1	4857

23557 7590 12/30/2005

SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
PO BOX 142950
GAINESVILLE, FL 32614-2950

EXAMINER	
VANDERVEGT, FRANCOIS P	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 12/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/045,180	BOUGUELERET ET AL.	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *53-61,71-73 and 75-105* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *53-57,61,71-73,75-79,83-88,92-97 and 101-103* is/are allowed.

6)☒ Claim(s) *58-60,80-82,89-91,98-100,104 and 105* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 05102004
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a divisional of U.S. Application Serial Number 09/486,580, which is a rule 371 continuation of PCT Serial Number PCT/FR98/01864.

Claims 1-52, 62-70, 74 have been canceled.

New claims 104-105 have been added.

Claims 53-61, 71-73 and 75-105 are currently pending and are the subject of examination in the present Office Action.

In view of Applicant's amendment filed October 6, 2005, the following ground of rejection is maintained only some of the claims previously rejected

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 58-60, 80-82, 89-91 and 98-100 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a WRITTEN DESCRIPTION rejection.

It was previously stated: "The claims are drawn to various embodiments that find their basis in the sequence of the full-length polypeptide instantly disclosed as SEQ ID NO: 3. The polypeptide of SEQ ID NO: 3 is encoded by the polynucleotide sequence of SEQ ID NO: 2. SEQ ID NO: 3 has been characterized in the instant specification as comprising at least three sub-domains: the signal peptide sequence of SEQ ID NO: 4, the proregion peptide sequence of SEQ ID NO: 5 and the mature peptide sequence of SEQ ID NO: 6, with the mature polypeptide having antimicrobial or cytotoxic activity.

The claims are drawn to embodiments of the claimed invention that are not adequately supported by the written description of the instant specification.

The claims are drawn to polynucleotides or vectors that encode a polypeptide comprising a fragment (or core) of at least 10 or 15 consecutive amino residues of SEQ ID NO: 3, 4, 5 or 6. The claims read upon a polynucleotide sequence that encodes any polypeptide sequence provided that it comprises any 10 or 15 contiguous amino acid sequence from SEQ ID NO: 3 or its sub-domains 4, 5, or 6. Other than the amino acid sequence of SEQ ID NO: 3 (or of its sub-domains 4, 5, or 6), there is no teaching regarding the composition of the amino acid sequence of the encoded polypeptide outside that 10 or 15 amino acid 'core' sequence -- i.e., one does not know what is to be added to the left or right thereof.

The claims are further drawn to polynucleotides encoding a polypeptide comprising an amino acid sequence at least 80% or 90% identical to the amino acid sequence of SEQ ID NO: 3 and the

fragments thereof that are disclosed as SEQ ID NOs: 4, 5, and 6. The specification discloses a single working example of a polypeptide that is naturally-occurring and has at least 80 or 90% identity to SEQ ID NO: 3; namely, the polypeptide of SEQ ID NO: 3 (inclusive of the fragments of SEQ ID NOs: 4, 5 and 6), which is encoded by the polynucleotide of SEQ ID NO: 2. However, the genus of polypeptides which are 80% identical to the 94 amino acid residue sequence of SEQ ID NO: 3 encompasses at least 18^{20} or 1.27×10^{25} different polypeptide molecules. The present disclosure falls short of the requirement to disclose an adequate number of species to claim such a broad genus.

> The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column).

Regarding the instant claim limitations, the specification does not appear to provide an adequate written description for the following reasons:

The instant specification discloses only a single protein comprising 10-15 amino acid fragments of SEQ ID NO: 3 or that shares 80 or 90 % identity with SEQ ID NO: 3, that single protein being the defensin protein of SEQ ID NO: 3. Additionally, the "full-length" polypeptides of SEQ ID NO: 4 and SEQ ID NO: 5 are included as being inadequately described to be included in a claim drawn to "comprising" SEQ ID NO: 4 or 5 because those peptides merely represent a signal peptide and a propeptide that is removed to generate the mature polypeptide of SEQ ID NO: 6. The peptides disclosed as SEQ ID NO: 4 and 5 do not possess the anti-microbial functions of SEQ ID NO: 6. Their only function that is disclosed in the specification is the delivery and placement of the mature polypeptide of SEQ ID NO: 6 such that the polypeptide of SEQ ID NO: 6 can carry out its disclosed function as an anti-microbial agent. Being recognized by an antibody is not a "biological activity," per se, because recognition is a function of the antibody, not of the target protein. SEQ ID NO: 4 and 5 have not been described in a manner that would demonstrate that the polypeptides could deliver any other mature polypeptide to its functional location.

In the absence some structural basis for that function that must be maintained by the members of the genus, the claimed invention is not described in such a way as to reasonably convey to one of ordinary skill in the art that the inventor, at the time the application was filed, had possession of the invention. See Regents of the University of California v. Eli Lilly & Co., 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Consequently, Applicant was not in possession of the instant claimed invention. See Regents of the University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Adequate written description of genetic material "'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." Id. 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim. Id. 43 USPQ2d at 1406. A description of what the genetic material does, rather than of what it is, does not suffice. Id.

Accordingly, the instant specification provides written descriptive support for nucleic acid molecules encoding a polypeptide:

- comprising SEQ ID NO: 3 or 6;
- consisting of SEQ ID NO: 3, 4, 5 or 6; or
- consisting of a fragment of SEQ ID NO: 3 or 6 comprising at least 10 or 15 consecutive amino acid residues thereof and having anti-microbial or cytotoxic activity."

Applicant's arguments filed October 6, 2005 have been fully considered but they are not persuasive.

Applicant has amended the claims and argues that the invention as claimed has sufficient descriptive support in the specification. However, the claims still read upon polynucleotides "comprising" SEQ ID NO: 4 or 5, a signal peptide and a proregion respectively. The specification has not disclosed these peptide segments in association with any polypeptide other that the mature polypeptide of SEQ ID NO: 3. there is no disclosure as to whether these peptide segments would be compatible with any other protein product.

In view of Applicant's amendment filed October 6, 2005, the following NEW GROUND of rejection has been necessitated.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 104 and 105 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 104 is ambiguous and unclear in reciting "said polynucleotide encodes a polypeptide comprising a mature peptide consisting of the sequence of SEQ ID NO: 3." SEQ ID NO: 3 is not a mature polypeptide, but is the pre-pro form of the mature peptide disclosed as SEQ ID NO: 6. SEQ ID NO: 3 comprises the signal peptide sequence of SEQ ID NO: 4 and the proregion peptide of SEQ ID NO: 5, both of which are cleaved off to yield the mature polypeptide of SEQ ID NO: 6.

Conclusion

4. Claims 53-57, 61, 71-73, 75-79, 83-88, 92-97 and 101-103 are allowed.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D.
Patent Examiner
December 16, 2005

David a Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644